

## REMARKS

### **I. Status of the claims and support for amendment**

Claims 1 and 17 are amended and new claim 26 is added.

Claims 1–11, 14, 15, 17, 21, and 26 are currently pending.

The “glucocorticoid” amendment of claim 17 is made merely to provide correct antecedent basis in the claim. The claim originally recited, in part, “wherein the dexamethasone dose”. However, there was no antecedent bases for use of the term “dexamethasone”, which is a type of glucocorticoid. Therefore, claim 17 has been amended to correct this defect and new claim 21 is added to cover the specific aspect of the invention specific where the glucocorticoid is dexamethasone.

Support for the addition of the phrase more “*and continues beyond the induction of lactation*” to claims 1 and 17 is found at page 13, line 13, through page 14, line10, of the application as originally filed.

### **II. Rejection under 35 U.S.C. § 103**

A. Claims 1–9, 14, 15, and 17 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Kumar *et al.* (*Indian J. Dairy Sci.*, 49:664–672 (1996)) in view of Collier *et al.* (*Journal of Dairy Science*, 58:1524–1527 (1975)). Specifically the rejection recites:

It would have been obvious to one of ordinary skill in the art at the time the invention was made to induce lactation in bovine heifers and reproductive culls according to the teachings of Kumar *et al.* by concurrent administration of 17  $\beta$ -estradiol and progesterone and bovine somatotropin, continuing administration of somatotropin for an extended period with reasonable expectation of success. Such expectation is raised by the disclosure that Collier *et al.* administered somatotropin for 10 days and noticed a significant effect. The references do not teach administration of somatotropin for 20 days or more but since a significant effect was seen in only 10 days, one of ordinary skill in the art would expect further administration of somatotropin to result in even more significant results. The precise ranges and dosages are not taught by the prior art but one of ordinary

skill in the art could determine the correct dosages using only routine experimentation, given the guidance by Kumar *et al.* and other references.

Applicant respectfully traverses.

MPEP 706.02(j) provides the following criteria that must be met in order to establish obviousness.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) (emphasis added).

For the reasons set forth below, it is Applicant's position that the combination of Kumar *et al.* and Collier *et al.* do not render the claims obvious.

Even taken in combination the cited references do not teach or suggest the extended administration of BST, especially beyond the induction of lactation, in order to induce milk production in heifers or non-pregnant cows. The combination of Kumar *et al.* and Collier *et al.* teaches only administration of 500 mg of BST "*on the very first day of hormone treatment*". When read in context, reference to Collier *et al.* (1993) does not, as suggested in the rejection clearly indicate that it is desirable to administer BST in order to induce lactation, especially in heifers or reproductive culls. The relevant part of Kumar *et al.* recites:

Talking into consideration the increase in udder parameters of successful and unsuccessful cases together it becomes clear that the mammary gland development in all the buffaloes was good and perhaps rBST administration had a positive effect on udder development. Collier *et al.* (1993) infused BST daily for 10 days in half of the udder of pregnant beef cows. The infusion of BST produced significant increase in mammary weight, dry weight, DNA and dry fat free weight. The results of this study support the contention that somatotropin has

a role in the overall development of mammary structures. Its role is not only confined to the ductal growth alone.

Kumar *et al.* p. 670, right-hand column. A more complete examination of the teachings of Kumar *et al.* makes several facts clear. First, the authors of Kumar *et al.* concede that their work does not clearly demonstrate that administration of rBST has a positive effect on udder development; hence the use of the qualifier “*perhaps*”. Therefore, it is improper to assert that the combination of the cited references provides a reasonable expectation of success for the instantly claimed invention. Instead, at best, the combination of cited references provides motivation to experiment. However, as set out in MPEP §2145 X.B. merely being “obvious to try” is not the standard under 35 U.S.C. § 103. Thus, the combination of the cited art fails the second requirement of MPEP 706.02(j), set out above.

The second fact made clear by a more complete reading of Kumar *et al.* is that there is no indication that administration of BST, especially administration extended beyond 20 days promotes the induction of milk production. Kumar *et al.* states that “*perhaps* rBST” helped udder development. The Collier *et al.* (1993) reference, cited in Kumar *et al.*, is less equivocal in that it provides definite evidence for the development of mammary structures. Nevertheless, neither reference comments on the likelihood that the BST was useful to induce lactation in dairy heifers and/or reproductive culls (see below).

Moreover, although the Collier *et al.* reference states that the cow udders were infused with BST for 10 days, there is no indication that this 10-day period was related to any other ongoing treatment. Accordingly, there is no basis for correlating the 10-day period with the beginning of the steroid treatment described in either Kumar *et al.* or Collier *et al.* (1975). Therefore it is Applicant’s position that the combination of the cited references provides no

motivation for administering BST for 10 days starting with the first day of steroid treatment. *A fortiori*, it cannot render it obvious to continue BST treatment for 20 days or more from the commencement of steroid treatment (and continued beyond the inducement of lactation), as described in the presently claimed invention.

Another fact made clear by a careful reading of Kumar *et al.* is that the reference provides no indication or suggestion that administration of BST is effective in dairy heifers and/or reproductive culls. The materials and methods section of Kumar *et al.* indicates that the test subjects for the experiments described therein were “[e]ight repeat breeding non-lactating multiparous Murrah buffaloes”. The test subjects in the Collier *et al.* (1993) reference cited in Kumar *et al.* were “**pregnant** beef cows”.

Thus, both Kumar *et al.* and Collier *et al.* (1993) describe treatment of either pregnant animals or animals that have been pregnant and are still capable of becoming so. There is no teaching or suggestion in the combination of the cited art that the use of BST for 20 or more days and beyond the induction of lactation would be effective to induce milk production in dairy heifers and/or reproductive culls.

Finally, there is no teaching or suggestion in the combination of the cited art that would motivate one of ordinary skill to continue administering BST to the animal beyond the induction of lactation, as required by the currently pending claims.

In view of the foregoing, it is Applicants position that the instant rejection fails to satisfy the requirements of MPEP 706.02(j). Accordingly, Applicant believes that the rejection of claims 1–9, 14, 15, and 17 under 35 U.S.C. § 103(a) has been overcome and may now properly be withdrawn.

B. Claims 10, 11, and 21 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Kumar *et al.* in view of Collier *et al.* (1975) and further in view of Miller *et al.*

Specifically the rejection alleges that:

[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to subject cows to the milk-stimulating photoperiods of Miller *et al.* while performing the method of Kumar *et al.* as modified by Collier *et al.* in order to obtain the benefits taught by Miller *et al.*

Applicant respectfully traverses.

For the reasons set out in part II. B., *supra*, Applicant contends that the combination of Kumar *et al.* and Collier *et al.* does not render claim 1 obvious. The addition of Miller *et al.* does nothing to change this. The primary contribution of this reference is the use of exposure to varying photoperiods. Since claims 10, 11, and 21 depend from and further limit claim 1 (depending directly and indirectly, respectively), there is nothing in the combination of the cited references that renders these claims obvious. Furthermore, as claim 21 does not include the photoperiod limitations, rejection of this claim is moot.

In view of the foregoing, Applicant believes that the rejection of claims 10, 11, and 21 has been overcome and may now properly be withdrawn.

### III. Request for withdrawal of the finality of rejection

The present Office Action recites that “Applicant’s amendment necessitated the new ground(s) of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP §706.07(a).” In view of the fact presented hereafter, Applicant respectfully traverses and requests reconsideration of the finality of the rejection.

The germane portion of MPEP §706.07(a) states that:

[u]nder present practice, second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is

neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p)."

MPEP §706.07(a) (emphasis added).

It is Applicant's position that the new grounds of rejection were not necessitated by Applicant's amendment of the claims, nor are they based on information submitted in an information disclosure statement submitted during the period set forth in 37 CFR 1.97(c). Taking the §706.07(a) criteria in reverse order, all references cited in the current rejections were provided in an Information Disclosure Statement filed prior to the first Office Action on the merits, so the finality of the rejection cannot be based on subsequently disclosed information.

Consequently, for the finality of the instant rejection to be proper it must be "necessitated" by an amendment that changes the claims such that the rejection could not have been made in the first Office Action. This is not the case.

The Office Action contains two rejections. The first rejections claims 1–9, 14, 15, and 17 under 35 U.S.C. § 103(a), as being obvious over Kumar *et al.* in view of Collier *et al.* The crux of this rejection is the allegation that it would have been obvious to administer somatotropin for 20 days or more, even though the combination of cited art teaches only 10 days. This rejection was not necessitated by the amendments to the claims. The limitations added to claims 1 and 17 were present in dependent claim 2 (which recited administration of somatotropin "for at least 20 days from day 0") and dependent claim 16 (which encompassed the limitation to reproductive dairy heifers and dairy reproductive culls, a subset of non-pregnant cows).

Claim 2 was amended to delete the "20 day" limitation incorporated into claims 1 and 17. Claims 3–9, 14, and 15 are either original claims or have been amended only to correct

typographical or grammatical errors (that is there has been no substantive amendments to these claims beyond those resulting from their dependence, directly or indirectly, on claim 1).

Thus, all limitations added to the claims were present in the original claim set and the first rejection could have been made in the July 2, 2003 Office Action.

Similarly, the second rejection could also have been made in the July 2, 2003 Office Action. The second rejection alleges that claims 10, 11, and 21 are unpatentable under 35 U.S.C. § 103(a) as being obvious over Kumar *et al.* in view of Collier *et al.* and Miller *et al.* The assertion of this rejection is that it would have been obvious “to subject cows to the milk-stimulating photoperiods Miller *et al.* while performing the method of Kumar *et al.* as modified by Collier *et al.* in order to obtain the benefits taught by Miller *et al.*” Claims 10 and 11 are original claims. That is they have not been amended from their form as initially filed. Consequently, there has been no modification of claims 10 and 11 that have necessitated their rejection in the instant Office Action.

Finally claim 21 has only been amended to change its dependence from claim 20 to claim 1 and to substitute the word “cull” for the word “cow”, in the next to last line. Moreover, claim 21 does not include, either directly or indirectly, a photo-period limitation. Accordingly, amendment of this claim did not necessitate its rejection in the current Office Action.

In view of the above discussion, Applicant asserts that the new rejections made in the current Office Action could have been made in the July 2, 2003 Office Action. All of the references currently cited were available then and all rejections made in the current Office Action address limitations that were present in the claims examined for the July 2, 2003 Office Action. Accordingly, Applicant contends that the current rejection fails to satisfy the

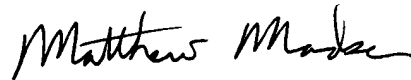
requirements for finality set out in MPEP §706.07(a). Therefore, Applicant respectfully requests that the finality of these rejections be withdrawn.

#### **IV. Conclusion**

In view of the foregoing Amendments and Remarks, Applicant believes that all outstanding objections and rejections have been resolved and that the case is in condition for allowance. Accordingly, Applicant respectfully requests favorable reconsideration of this application and issuance of a Notice of Allowance therefor.

The Examiner is invited to contact the undersigned attorney at (713) 787-1589 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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